510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K062575

1. Date of Summary: August 28, 2006

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   Tel: 732-274-1000
   Fax: 732-274-1010

3. Device Name:
   Trade Names: AccuSign® RC-DOA 10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   StatusFirst® DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   Common or Usual Name: Immunoassay for detection of abused drugs in human urine
   Classification Name: Drugs of abuse test systems, Clinical toxicology test system

4. Identification of legally marketed device to which claims equivalence:
   k983501: AccuSign® DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   by Princeton BioMeditech Corporation

5. Device Description:
   The AccuSign® RC-DOA 10 test device is a simple immuno-chromatographic test for the rapid, qualitative detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, amphetamine and/or their metabolites in human urine. The test result can be read visually or with DXpress reader (k050955).

6. Intended Use:
   AccuSign® RC-DOA 10 is intended to use for the qualitative detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, amphetamine, and/or their metabolites in human urine to assist in screening of drugs of abuse samples. For in vitro diagnostic use. The detecting cut-off concentrations are as follows:

   | MET | D-Methamphetamine | 1000 ng/mL |
   | OPI | Morphine | 300 ng/mL |
   | COC | Benzoyleconine | 300 ng/mL |
   | THC | 11-nor-A9-9-carboxylic acid | 50 ng/mL |
   | PCP | Phencyclidine | 25 ng/mL |
   | Benzodiazepine | Oxazepam | 300 ng/mL |
   | Barbiturate | Secobarbitral | 300 ng/mL |
   | Methadone | Methadone | 300 ng/mL |
   | TCA | Nortriptyline | 1000 ng/mL |
   | AMP | D-Amphetamine | 1000 ng/mL |
This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method.

7. Substantial Equivalence:
AccuSign® RC-DOA 10 is substantially equivalent in intended use, principle and performance to the current k983501, AccuSign® DOA 10. Both assays are in vitro immuno-chromatographic assays with an intended use for the qualitative detection of drugs of abuse in human urine to assist in screening of drugs of abuse samples. The two products are identical and use the same formula and manufacturing processes with the same reagents. The only difference is AccuSign® RC-DOA 10, Reader reading compatible, allows an optical result reading method to customers by using a reader, DXpress, for result reading; on the other hand, AccuSign® DOA 10 is a visual read only test.

Conclusion: The device is substantially equivalent to a legally marketed device k983501.
**Substantial Equivalence**

AccuSign® RC-DOA 10 test is substantially equivalent to AccuSign® DOA 10, k983501 by Princeton BioMeditech Corporation.

The table below compares the AccuSign® RC-DOA 10 test to the predicate devices.

<table>
<thead>
<tr>
<th>Item</th>
<th>AccuSign®-DOA 10 (Predicate)</th>
<th>AccuSign® RC-DOA 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>For the qualitative detection of 10 kinds of drugs of abuse in human urine</td>
<td>For the qualitative detection of 10 kinds of drugs of abuse in human urine</td>
</tr>
<tr>
<td>Assay Principle</td>
<td>Lateral flow Immuno-chromatographic assay</td>
<td>Lateral flow Immuno-chromatographic assay</td>
</tr>
<tr>
<td>Test Procedure</td>
<td>Add 3 drops of urine into the sample well.</td>
<td>Add 3 drops of urine into the sample well.</td>
</tr>
<tr>
<td>Result reading time</td>
<td>5-10 min</td>
<td>5 min</td>
</tr>
<tr>
<td>Method of result reading</td>
<td>Visual Read only</td>
<td>DXpress reader (k050955) or visual</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Human urine</td>
<td>Human urine</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>3 drops</td>
<td>3 drops</td>
</tr>
</tbody>
</table>
| Detection Cutoff      | D-Methamphetamine 1000  
Morphine 300  
Benzoylecegonine 300  
11-nor-Δ⁹-carboxylic acid 50  
Phencyclidine 25  
Oxazepam 300  
Secobarbital 300  
Methadone 300  
Nortriptyline 1000  
D-Amphetamine 1000  | D-Methamphetamine 1000  
Morphine 300  
Benzoylecegonine 300  
11-nor-Δ⁹-carboxylic acid 50  
Phencyclidine 25  
Oxazepam 300  
Secobarbital 300  
Methadone 300  
Nortriptyline 1000  
D-Amphetamine 1000  |
Princeton BioMeditech Corporation
c/o Kyung-Ah Kim
4242 US Route I
Monmouth Junction, NJ 08852-1905

Re: k062575
Trade/Device Name: AccuSign ®RC-DOA 10 (MET/OPI/COC/THE/PEP/BZO
BAR/MTD/TCA/AMP
Regulation Number: 21 CFR 862.3160
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: LAG, DJG, DIO, DKE, DKZ, DIS, DJR, LFI, LCM, JXM
Dated: October 1, 2007
Received: October 2, 2007

Dear Dr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): k062575

Device Name: AccuSign®RC-DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine, opiates, cocaine metabolite, THC metabolite, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, and amphetamine in human urine to assist in screening of drug of abuse samples. The detecting cut-off concentrations are as follows:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Cutoff Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>MET D-Methamphetamine</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>OPI Morphine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>COC Benzoylecgonine</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>THC 11-nor-Δ9-carboxylic acid</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>PCP Phencyclidine</td>
<td>25 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepine Oxazepam</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Barbiturate Secobarbital</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>Methadone Methadone</td>
<td>300 ng/mL</td>
</tr>
<tr>
<td>TCA Nortriptyline</td>
<td>1000 ng/mL</td>
</tr>
<tr>
<td>AMP D-Amphetamine</td>
<td>1000 ng/mL</td>
</tr>
</tbody>
</table>

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS)/High performance liquid chromatography (HPLC, for TCA) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of GDRH, Office of In Vitro Diagnostic Devices (OIVD)